

**PART III: CONSUMER INFORMATION**

Pr **GIOTRIF**<sup>®</sup>  
Afatinib Tablets

**This leaflet is part III of a three-part "Product Monograph" published when GIOTRIF was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about GIOTRIF. Contact your doctor or pharmacist if you have any questions about the drug.**

**ABOUT THIS MEDICATION**

**What the medication is used for:**

GIOTRIF is used to treat people with certain types of non-small cell lung cancer that have spread to other parts of the body.

The types include:

- adenocarcinoma which has an epidermal growth factor receptor (EGFR) gene mutation
- squamous cell cancer

**What it does:**

GIOTRIF works by permanently blocking a group of proteins which are involved in the growth and spread of cancer cells. Studies have shown that GIOTRIF may slow the progression of your cancer and in certain patients it may prolong your survival.

**When it should not be used:**

If you are hypersensitive (allergic) to afatinib or any of the other ingredients of GIOTRIF.

**What the medicinal ingredient is:**

Afatinib (as afatinib dimaleate)

**What the non-medicinal ingredients are:**

colloidal anhydrous silica, crospovidone, hypromellose, indigocarmine aluminium lake (only used for 40 mg and 30 mg tablets), lactose monohydrate, macrogol, magnesium stearate, microcrystalline cellulose, polysorbate, talc, and titanium dioxide

**What dosage forms it comes in:**

GIOTRIF is available in three different strengths:

- 20 mg tablets are white to slightly yellowish, round, biconvex, bevel-edged tablets;
- 30 mg tablets are dark blue, round, biconvex, bevel-edged tablets;
- 40 mg tablets are light blue, round, biconvex, bevel-edged tablets.

One side of the tablets is debossed with the code "T20", "T30" or "T40". The other side has the Boehringer Ingelheim company symbol "BI".

GIOTRIF is available in packs containing 1, 2 or 4 pouches. Each pouch contains a blister card of 7 unit dose tablets. Each blister card is packed together with a desiccant sachet in an aluminium pouch.

**WARNINGS AND PRECAUTIONS**

**Serious Warnings and Precautions**

**GIOTRIF is taken while under the care of a doctor who has experience with anti-cancer drugs.**

**Your doctor may test for your mutation status.**

**GIOTRIF can cause serious reactions, even death. Some of these reactions include:**

- **Diarrhea**
- **Skin rash**
- **Trouble breathing, cough and fever**
- **Liver problems**

**BEFORE you use GIOTRIF talk to your doctor or pharmacist if you:**

- have liver disease or kidney disease;
- have a dairy or lactose intolerance;
- have a history of lung inflammation (interstitial lung disease);
- have a history of severe dry eye or eye inflammation-(keratitis) or use contact lenses;
- have heart problems;
- have any other medical conditions;
- are pregnant, or plan to become pregnant. GIOTRIF may-harm your unborn baby;
- are breastfeeding. GIOTRIF may pass into your breast milk and harm your baby;
- are female and have a low body weight of less than 50 kg.

You should not become pregnant while taking GIOTRIF. Women who are able to become pregnant should use birth control during treatment and for at least 2 weeks after stopping GIOTRIF. Talk to your doctor about the birth control methods that may be right for you.

If you become pregnant, tell your doctor right away.

Avoid exposure to the sun while you are taking GIOTRIF. Rash or acne may occur or worsen in areas exposed to the sun. You may

burn more easily and get severe sunburns. To help protect against skin problems wear clothes that protect your skin, including your head, face, hands, arms, and legs and use a sunscreen.

Caution is required when driving a car as some side effects may affect your ability to do so.

## INTERACTIONS WITH THIS MEDICATION

Tell your doctor about all the drugs you take. This includes prescription and non-prescription drugs, vitamins, and herbal supplements. GIOTRIF may interact with other medications. This may cause serious side effects.

Know the medicines you take. Keep a list of your drugs and show it to your doctor and/or pharmacist each time you get a new drug.

Discuss with your doctor or pharmacist if you take any of the following:

- Antifungals (such as ketoconazole, itraconazole);
- Antibiotics (such as erythromycin);
- Drugs to treat tuberculosis (TB) (such as rifampicin);
- Drugs to treat HIV-AIDS and viral infections (such as nelfinavir, saquinavir);
- Calcium channel blockers (such as verapamil);
- Antiarrhythmics (such as quinidine, amiodarone);
- Anticonvulsants (such as carbamazepine, phenytoin and phenobarbital);
- Cancer drugs;
- Immunosuppressants (such as tacrolimus);
- Statins used to lower cholesterol;
- St. John's Wort.

## PROPER USE OF THIS MEDICATION

### Usual Dose:

The usual dose is one 40 mg tablet taken orally once a day.

If you have severe kidney problems, the usual starting dose is 30 mg a day.

- Take the tablet once daily at about the same time each day.
- Take GIOTRIF on an empty stomach at least 1 hour before or 3 hours after eating.
- Do not break or crush the tablet.
- Swallow the tablet whole with a glass of water.

Always take GIOTRIF exactly as your doctor has instructed you. Check with your doctor or pharmacist if you are unsure.

### Overdose:

If you think you have taken too much GIOTRIF, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

### Missed Dose:

If you miss a dose, take it as soon as you remember. If it is close to your next dose (within 8 hours), skip the dose and just take your next dose at your regular time. Do not take 2 doses of GIOTRIF at the same time.

### Lost Dose:

If you throw up after taking GIOTRIF, do NOT take a replacement tablet. Just take your next dose at your regular time.

Do not take GIOTRIF for a condition for which it was not prescribed. Do not give GIOTRIF to other people, even if they have the same condition.

## SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, GIOTRIF can have side effects.

**The very common side effects (more than 1 out of 10 patients) include:**

- Diarrhea;
- Inflammation of the lining of the mouth (stomatitis);
- Infection of the nail bed (paronychia);
- Loss of appetite;
- Nosebleed;
- Rash;
- Skin eruptions resembling acne;
- Itchy/scratchy skin;
- Dry skin.

**The common side effects (less than 1 out of 10 patients) include:**

- Inflammation of the urinary bladder resulting in a burning sensation during urination and frequent urgent need to urinate (cystitis);
- Excessive loss of body water (dehydration);
- Low blood potassium levels;
- Taste disturbance or loss of taste;
- Inflammation or infection of the membrane lining the eyelids (conjunctivitis);
- Dry eye;
- Runny nose;
- Indigestion, stomach pain;
- Inflammation of the lips;
- Redness, swelling, and pain on the palms of the hands and/or the soles of the feet (Palmar-plantar erythrodysesthesia syndrome);
- Muscle spasm;
- Kidneys not working properly or failing;
- Fever or high temperature;
- Loss in weight;
- Increase in liver enzymes;
- Inflammation of the cornea;
- Inflammation or scarring of the lungs (interstitial lung disease);

- Nail disorders.

**Seek medical advice promptly if the following signs or symptoms occur:**

**Diarrhea:**

Talk to your doctor before you take GIOTRIF on how best to control and minimize any symptoms of diarrhea.

Your doctor should prescribe diarrhea medicine before you start GIOTRIF therapy. You should not change your medicine without talking to your doctor. You should have the medicine with you at all times.

If you have diarrhea, call your doctor as soon as possible.

Diarrhea should be treated as soon as it starts. Take the diarrhea medicine exactly as your doctor has told you. Drink plenty of fluids. If you don't drink enough fluids, you could become dehydrated and it could affect your kidneys. Call your doctor right away if your diarrhea becomes worse.

To help control your diarrhea you should modify your diet to include bananas, rice, apple sauce and toast (BRAT diet), and increase your fluid intake with clear liquids. The daily fluid intake should be greater than 2 litres a day (about 8 glasses of 250 mL) to avoid dehydration. Some fluids should contain sugar or salt to avoid low blood sugar or salt. The use of caffeinated drinks should be avoided. Make a follow-up appointment with your doctor. You should avoid foods that contain lactose, are greasy, spicy and/or fried, and are difficult to digest.

**Skin Reactions:**

It is important to seek treatment for a rash as soon as you notice it. Take medicines to help your rash exactly as your doctor tells you to. Seek medical attention right away if your rash becomes severe (for example, you have peeling or blistering of the skin).

**Interstitial Lung Disease:**

Tell your doctor right away if you have any new or worsening lung symptoms, or any combination of the following symptoms: trouble breathing or shortness of breath, cough, and fever.

**Liver Problems:**

Tell your doctor right away if you get any of these symptoms of a liver problem during treatment:

- your skin or the whites of your eyes turn yellow.
- you feel tired.
- your urine turns dark or brown (tea colored).
- you have nausea or vomiting.
- you have decreased appetite.
- you have a pain on the right side of your stomach.
- you bleed or bruise more easily than normal.

**Eye Problems:**

Tell your doctor right away if you get any of these symptoms during treatment:

- eye pain, swelling, or redness;
- blurred vision or other vision changes.

**Paronychia:**

This is a painful, red, swollen area around the nail, often at the cuticle or at the site of a hangnail or other injury. It can be caused by bacteria, yeast or fungus. Nail changes may occur. For example, the nail may look detached, abnormally shaped, or have an unusual color. Your doctor will prescribe the proper medicine to treat your nails. You should be careful to take good care of your skin. Avoid injury to your nails or finger tips. Avoid harsh chemicals such as soap, detergent, and nail products. Keep your hands clean and dry.

**Stomatitis:**

This is an inflammation anywhere in the mouth and includes the inside of the cheeks, gums, tongue, lips, and roof of the mouth (palate). Your doctor will be able to advise you on how best to treat it.

GIOTRIF can affect your heart function and cause abnormal blood test results. Your healthcare provider will monitor your heart and do blood tests. This occurs before you start taking GIOTRIF and periodically during treatment. The doctor will interpret the results.

<b>SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM</b>				
<b>Symptom / effect</b>		<b>Talk with your doctor or pharmacist</b>		<b>Stop taking drug and call your doctor or pharmacist</b>
		<b>Only if severe</b>	<b>In all cases</b>	
<b>Very common</b>	<b>Diarrhea</b>		✓	
	<b>Rash</b>		✓	
	<b>Inflammation of the lining of the mouth</b>		✓	
	<b>Infection of the nail bed</b>		✓	
<b>Common</b>	<b>Abnormal laboratory test results</b>		✓	
	<b>Little or no urine output</b>		✓	
	<b>Inflammation of the cornea (eye pain and worsening/loss of vision)</b>		✓	
	<b>Inflammation of the lungs (sudden difficulty in breathing with cough or fever)</b>		✓	

*This is not a complete list of side effects. For any unexpected effects while taking GIOTRIF, contact your doctor or pharmacist.*

## HOW TO STORE IT

Store at 15 – 30°C.

Open only one pouch at a time until all the tablets in the blister card are consumed before opening the next pouch.

Store the blister card in the original package in order to protect from moisture and light.

Store in a safe place out of the reach of children.

Do not use GIOTRIF after the expiry date on the blister pack.

Remember to return any unused GIOTRIF to your pharmacist.

### Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

## MORE INFORMATION

### If you want more information about GIOTRIF:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>), the manufacturer's website (<http://www.boehringer-ingelheim.ca>), or by calling the manufacturer, Boehringer Ingelheim (Canada) Ltd., at: 1-800-263-5103, extension 84633.

This leaflet was prepared by Boehringer Ingelheim (Canada) Ltd. The information in this leaflet is current up to the time of the last revision date shown below, but more current information may be available from the manufacturer.

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